

# Stacy Swartz



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June 06, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration,  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852.  
Docket No. 99D-0557

To Whom It May Concern:

I am writing in reference to Docket number 99D-0557, regarding nonhuman primate xenotransplants. The bottom line in this issue is that clinical protocols proposing the use of nonhuman primate xenografts should not be submitted to the FDA until sufficient scientific information exists addressing the risks posed by nonhuman primate xenotransplants.

I understand that the FDA is saying that it would not approve any primate xenografts at this time, but is encouraging further research on primates to study virus transmission to humans. However, the FDA is not ruling out other species, like pigs, in xenotransplants.

I would just like to say that this poses problems for the human population for many reasons. First, responsible health authorities would ban all xenotransplants outright, regardless of the species, particularly because of the threats of inter-species virus transmission. Second, pigs are being considered as the source animal of choice for xenotransplants, but there is no evidence that pigs are any safer than nonhuman primates. We have plenty of evidence that pig viruses would be just as dangerous as nonhuman primate viruses (i.e. influenza, PERVs, paramyxovirus, and earlier this year, the Nipah (Hendra-like virus) in Malaysia that has resulted in hundreds of human infections, 98 human deaths, and 640,500 pigs slaughtered since March 20th). Third, the US should follow Europe's lead. In January 1999, the Council of Europe, representing 40 European countries, recommended a world-wide ban on xenotransplants. Fourth, there are safer and more humane alternatives to xenotransplantation that are not being explored by regulatory authorities. These include aggressively promoting preventive medicine, and increasing human organ donation rates as many European countries have successfully done through various legislative schemes. And finally, the US General Accounting Office published a report on Organ Donation in April 1998 which revealed an untapped donor pool of 150,000 people in the US. The Department of Health and Human Services should fully investigate the points made in that report before allowing xenotransplants to go forward.

Sincerely,

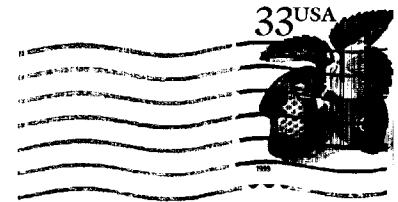


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